Remarks

Claims 1, 3, 5, 7, 9, and 11-64 are in this application.

It is noted that claims 1, 3, 5, 7, 9, 11-19 and 64 are allowed.

The Examiner maintains the rejection of claims 30-35 and 52-55 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

The Examiner has taken the position that there is no antecedent basis for dementia, cancer and inflammation in these claims because claim 24 refers to diseases in which insulin resistance is the underlying pathophysiological mechanism. The Examiner states that "Applicants have not asserted and it is not art recognized that the three rejected diseases are so mechanistically related."

This statement is incorrect. In the previous response, applicants discussed and provided a number of references which established the relationship between insulin resistance and dementia, cancer and inflammation.

For example, Watson, G.S. et al. CNS Drugs 2003: 17(1):27-45 cited in the previous response describes evidence that "suggests that an increased prevalence of insulin abnormalities and insulin resistance in Alzheimer's disease may contribute to the disease pathophysiology and clinical symptoms." The abstract also discloses that the insulin plays a role in memory functions. It is stated in the abstract that "The increased occurrence of insulin resistance in Alzheimer's disease and the numerous mechanisms through which insulin may affect clinical and pathological aspects of the disease suggest that improving insulin effectiveness may have therapeutic benefit for patients with Alzheimer's disease."

Claude Messier, et al. Behavioural Brain Research 75(1996):1-11 also cited in the previous response discusses the relationship between Alzheimer's disease and glucose and concludes in the second column on page 7 "There are indications that treatment of altered glucoregulation in AD patients with anti-diabetic drugs could lead to small but significant improvements in cognitive function."

In addition, applicants respectfully draw the Examiner's attention to the following references which describe a relationship between dementia (Alzheimer's disease) and insulin resistance; "The Diabetes-Dementia Connection", Clinician Reviews, March 2000; and J. Kuusisto, et a. British Medical Journal, No. 7115, Vol. 315, October 25, 1997.

Applicants respectfully draw the Examiner's attention to the following references Isaksson et al., Pancreatology 2002, 217-361, Lois Baker, University of Buffalo Reporter, Vol. 32, No.16, January 18, 2001; Gabe Mirkin, Report, 6502,

CBS Radio News , May 14, 1995, and Hsing, et al. J. National Cancer Institute, 2003 January 1, 95(1):67-71 which describe a relationship between different forms of cancer and insulin resistance.

Applicants respectfully draw the Examiner's attention to the following reference Festa, et al. Circulation, 2000 July 4:102(1):42-7 which describes a relationship between inflammation and insulin resistance.

Therefore, since applicants have again shown that it is art recognized that cancer, dementia and inflammation are related to insulin resistance, it is respectfully requested that this rejection be withdrawn.

The Examiner has rejected claims 20-63 under 35 USC 112, first paragraph. Applicants respectfully traverse this rejection.

The Examiner states that these claims are enabling for type II diabetes, insulin resistance and hypercholesteremia. Applicants have shown that the diseases and conditions defined in claims 20-63 are linked to type II diabetes, insulin resistance and hypercholesteremia and thus one skilled in the art could treat these conditions without undue experimentation.

The Examiner states that determining if any particular claimed compound would treat any particular PPARα or PPARγ related disease would require synthesis of the compound, formulation into a suitable dosage form and subjecting it to clinical trials with a number of fundamentally different diseases, or to testing them in an assay known to be correlated to clinical efficacy of such treatment. The steps that the examiner has outlined are not required for meeting the enablement requirement in a patent application.

There is no requirement that a patent application include a working example and no requirement that an application include *in vivo* data and especially not human data.

The cost of obtaining US FDA approval to market a drug is extremely expensive upwards of $25 million. It would be extremely rare for a company to have completed preclinical trials and have filed an Investigational New Drug application (IND) before filing a patent application. Therefore, the lack of human data in this application cannot be used as a basis for rejecting claims for lack of enablement.

The Examiner states that the artisan using applicants invention would be a physician with a MD degree and several years of experience. The applicants will not comment at this time on whether the Examiner's statement is true and whether or not applicants' agree or disagree with the statement. However, it is extremely unlikely that a physician with a MD degree would recommend that a patient use a compound of formula (I) according to any one of claims without the compound having been approved by the US FDA.

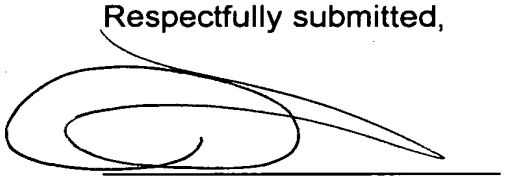
Applicants respectfully request that this rejection be withdrawn.

Based on the disclosure in this application and the knowledge of one skill in the art it is clear that one of skill in the art would be able to make and use the invention. Therefore, the enablement requirement is met.

It is respectfully requested that this rejection be withdrawn.

Accordingly, applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,



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